

Elizabeth Kavalier, M.D.

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IN THE CIRCUIT COURT
TWENTY-SIXTH JUDICIAL CIRCUIT
CAMDEN COUNTY, MISSOURI

- - -

DONALD BUDKE	:	
Plaintiff,	:	
v.	:	
JOHNSON & JOHNSON, a NEW	:	
Jersey Corporation, ETHICON	:	
INC., a New Jersey Corporation,	:	
GYNECARE WORLDWIDE, a division	:	
of Ethicon, Inc., BECKY	:	
SIMPSON, M.D., P.C., d/b/a	:	Cause No.
LAKE AREA WOMEN'S CENTER	:	10CM-CC00085
and BECKY SIMPSON, M.D.,	:	
Defendants.	:	

- - -

OCTOBER 14, 2014

- - -

Videotaped deposition of
ELIZABETH KAVALER, M.D., taken pursuant
to notice, was held at the law offices of
Bryan Cave LLP, 1290 Avenue of the
Americas, New York, New York 10104,
commencing at 10:37 a.m., on the above
date, before Amanda Dee Maslynsky-Miller,
a Certified Realtime Reporter and Notary
Public in and for the State of New York.

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1 product and how to compare it to
2 the way I was -- I was shown how
3 to use it.

4 But a lot of the information
5 in there is not something that I'm
6 looking to Ethicon to tell me.

7 BY MR. SLATER:

8 Q. I understand you're smart
9 and you don't need it, but other doctors
10 may not --

11 MR. BALL: I move to strike
12 the --

13 BY MR. SLATER:

14 Q. Let me ask you this --

15 MR. BALL: -- the
16 argumentative preamble.

17 BY MR. SLATER:

18 Q. -- do you think Ethicon has
19 an obligation, and had an obligation,
20 with the PROLIFT® IFU that when they put
21 information in it, that Ethicon thought
22 the information was truthful?

23 MR. BALL: Object to the
24 form.

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1 THE WITNESS: I don't put
2 this much thought into the IFU. I
3 don't know any surgeons who do put
4 that much into the IFU.

5 BY MR. SLATER:

6 Q. You don't have an opinion on
7 that?

8 A. I don't really have much of
9 an opinion on the IFU.

10 Q. Okay. If I understand
11 correctly, you, in your practice, didn't
12 even the read the section of the warnings
13 and indications and adverse reactions;
14 that wasn't even something that you
15 looked at, correct?

16 MR. BALL: Object to the
17 form.

18 THE WITNESS: I read it. I
19 looked at it. But that wasn't the
20 basis for which I would use it or
21 not use it.

22 BY MR. SLATER:

23 Q. Did I ask you if that was
24 the basis for which you would use it or

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1 MR. SLATER: So we have a
2 disagreement.

3 MR. BALL: -- you're right.

4 MR. SLATER: It doesn't
5 matter. That's why we have a
6 judge.

7 BY MR. SLATER:

8 Q. You never used the patient
9 brochure in your practice, right?

10 A. That's right.

11 Q. As you sit here now, you
12 have no opinions about whether or not the
13 information in the patient brochure was
14 adequate or not, correct?

15 MR. BALL: Object to the
16 form.

17 THE WITNESS: I've read it.
18 I think it's adequate. I don't
19 know what the obligations are, but
20 it's adequate.

21 So I have read it. I didn't
22 use it. And I think it's adequate
23 information.

24 BY MR. SLATER:

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1 **Q.** And what's the standard by
2 which you're judging whether or not the
3 information in the patient brochure is
4 accurate? Define for me that standard.

5 **A.** Well, "adequate" is a
6 judgment, right? It's a subjective
7 assessment of what's right or wrong.

8 **Q.** So it's your personal
9 opinion?

10 **A.** Right. So adequate, to me,
11 is that it covers the bases, it gives you
12 a general idea of what's involved. But
13 it's really a tool for a conversation
14 between the patient and the doctor.

15 **Q.** Something you never used it
16 for, right?

17 **A.** I never used it for that
18 because I did my own.

19 **Q.** Let me ask you this -- to go
20 back to some of the questions I asked you
21 on the IFU, I'm going to ask a few of
22 them for the patient brochure.

23 When Ethicon provided
24 information in the patient brochure for

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1 **A.** Can you be more specific in
2 what you want me to answer?

3 **Q.** Sure.

4 With regard to the
5 various -- I'll ask it even more
6 specific.

7 With regard to the various
8 prolapse meshes you've used over the
9 years, do you know the difference in pore
10 sizes between the different devices?

11 **A.** Not specifically. But I
12 know they are all within the same --
13 they're all Type 1 meshes, all their pore
14 sizes are of a certain size that's
15 acceptable for vaginal surgery. So as
16 long as they all are within that sort of
17 standard, then it's an appropriate
18 vaginal application.

19 **Q.** You believe that as long as
20 a mesh has pore sizes of at least 75
21 microns that's acceptable?

22 **A.** Yes. But most of them are
23 considerably larger. The weave is -- the
24 weave is considerably larger.

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1 **Q.** Have you ever studied the
2 question of what happens to the pores of
3 the PROLIFT® once tension is placed on
4 them and they're put into the body?

5 **A.** Studied is -- I wouldn't
6 use -- I am not sure what you mean by
7 "studied," but I've certainly done a lot
8 of prolapse -- PROLIFT® surgeries and
9 seen the way the mesh is integrated.

10 So I don't know what -- I'm
11 not sure what the question is.

12 **Q.** Do you know whether or not
13 the pores in the PROLIFT® collapse down
14 when tension is placed on the PROLIFT® in
15 actual use?

16 **A.** In the patient's body?

17 **Q.** Yes.

18 **A.** I don't have that
19 experience. It gets integrated and
20 incorporated and there's no -- the
21 collapse, it doesn't -- I don't know what
22 you mean by "collapse." It gets
23 incorporated.

24 **Q.** When tension is placed on

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1 would -- for me what the -- the meaning
2 of that is. But is that what you mean,
3 what it means to me?

4 Q. No. I want to know what --
5 if you understand, from a scientific
6 basis, based on the information that's
7 out there in the medical and scientific
8 community, among people who study that
9 question, if you know the answer to it.

10 MR. BALL: Object to the
11 form.

12 THE WITNESS: I understand
13 the importance of pore size in
14 mesh. That I understand.

15 BY MR. SLATER:

16 Q. I asked about 1 milliliter.
17 Do you know the importance of that for
18 clinical implications?

19 A. I do.

20 Q. And what is your
21 understanding?

22 A. My understanding is that
23 mesh with a certain pore size will allow
24 macrophages and cells to get through the

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1 mesh so that bacteria can be eliminated.

2 Q. In terms of how scar tissue
3 forms, do you have any knowledge about
4 the significance or lack of significance
5 of a 1 millimeter pore size?

6 MR. BALL: Object to the
7 form.

8 THE WITNESS: In terms --
9 can you define what you mean by
10 "scar tissue"?

11 BY MR. SLATER:

12 Q. Yes. Fibrotic tissue that
13 forms as part of the inflammatory
14 response to the foreign body.

15 Do you have any knowledge of
16 whether or not a 1 millimeter pore size
17 has any significance for how that scar
18 tissue will form on the mesh?

19 A. I don't use --

20 MR. BALL: Object to the
21 form.

22 THE WITNESS: Yeah, "scar
23 tissue" is not some -- a
24 terminology -- a term that I would

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1 MR. SLATER: Objection.

2 Your questions are leading.

3 MR. BALL: Okay. All right.

4 I'll start over. Let me finish

5 them, though. You got me all --

6 you got me all confused because I

7 hadn't finished.

8 MR. SLATER: I thought you

9 were done. You asked for a list.

10 Well, it's multi-part too. Ask

11 Bettina, she knows. Compound

12 queen.

13 BY MR. BALL:

14 Q. Have you -- have you

15 reviewed the patient brochure, the IFU

16 and the professional education materials

17 in existence before Ms. Budke's surgery?

18 MR. SLATER: Objection.

19 Foundation. Leading.

20 MR. BALL: Go ahead and

21 answer.

22 THE WITNESS: I have

23 reviewed those materials.

24 BY MR. BALL:

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1 **Q.** Do you believe that they
2 were adequate for a -- for the purposes
3 of a surgeon like you, in terms of
4 determining the risks and benefits of
5 PROLIFT® and counseling your patients?

6 MR. SLATER: Objection.

7 You can answer.

8 THE WITNESS: Yes, they were
9 adequate.

10 BY MR. BALL:

11 **Q.** Okay. Then, last question,
12 in your experience, does the mesh used in
13 PROLIFT® potentiate infection less than
14 other foreign materials?

15 MR. SLATER: Objection.

16 MR. BALL: Go ahead.

17 THE WITNESS: Yes, it does.

18 The PROLIFT® mesh is a Type 1
19 polypropylene mesh, which is --
20 has a very low infection rate, as
21 evidenced by the literature.
22 We've used prolene sutures for
23 years. And it potentiates
24 infection much less than most

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1 CERTIFICATE

2

3

4 I HEREBY CERTIFY that the
5 witness was duly sworn by me and that the
6 deposition is a true record of the
7 testimony given by the witness.

8

9

10

Amanda Maslynsky-Miller

11

Certified Realtime Reporter

Dated: October 15, 2014

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18 of this transcript does not apply to any
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20 unless under the direct control and/or
21 supervision of the certifying reporter.)

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